

**REMARKS**

The final Office Action of March 20, 2007, has been received and reviewed.

Claims 1, 4-18, 50, and 53-78 are currently pending and under consideration in the above-referenced application, each standing rejected.

Reconsideration of the above-referenced application is respectfully requested.

**Claim Objections**

The Office has objected to claims 68 and 75 for use of the terms “an” and “a” before “arginine” and “lysine,” respectively.

The terms “an” and “a” have been included to indicate to one of ordinary skill in the art that arginine or lysine molecules may be present in the claimed composition, or that other molecules that include arginine or lysine residues may be present in the claimed composition. This intent is evidenced by claims 69 and 77, which further limit the lysine and arginine that are present in a particular embodiment of the compositions to which claims 68 and 75 are respectively directed.

In any event, it is proposed that claims 68 and 75 be revised to more clearly state their originally intended scopes. It is respectfully submitted that these revisions do not narrow the scope of either claim 68 or claim 75.

It is respectfully requested that the objections to claims 68 and 75 be withdrawn.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 4-18, 50, 53-67, 69-73, 77 and 78 have been rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter that is purportedly indefinite.

Claims 1, 4-18, 50, 53-67, 71, and 73 stand rejected because the recitation of at least one pathogen “associated with” a cardiovascular disorder was believed to be indefinite. It is proposed that the phrase “associated with,” which was used in claims 1, 50, 71, and 73, be replaced with the more definite phrase “that directly causes.”

In rejecting claims 1 and 50 and their respective dependent claims, the Office has asserted that the phrase “treated cardiovascular disorder” is indefinite. It is respectfully submitted that

one of ordinary skill in the art would understand from the plain language of independent claims 1 and 50 that the “treated cardiovascular disorder” is a disorder that is to be treated with the claimed compositions. In an effort to advance prosecution, it is proposed that independent claims 1 and 50 be revised to recite a “cardiovascular disorder treated with the composition.”

Claims 69, 77, and 78 have been rejected because claims 68 and 75 are drawn to compositions that include arginine and lysine, while claims 69 and 77, respectively, recite compositions that include magnesium arginate and magnesium lysinate. It is respectfully submitted that one of ordinary skill in the art would consider magnesium arginate to be an acceptable form of arginine and magnesium lysinate to be a suitable form of lysine.

Claim 69 has also been rejected for reciting “lysing” where the term “lysine” was intended. It is proposed that claim 69 be amended to correct this typographical error, and submitted that since the revision to claim 69 merely corrects an apparent typographical error, it does not alter the scope of claim 69.

Claim 70 has been rejected because the term “amount” is considered to be indefinite. It is respectfully submitted that, regardless of the measure of an “amount,” one of ordinary skill in the art would readily understand from the plain language of claim 70 that, to fall within the scope of claim 70, a composition must include a transfer factor-including preparation and vitamin C in substantially the same measure (*e.g.*, volume, weight, mass, etc.) and “amount.”

It is also respectfully submitted that, with respect to the recitation of “a first amount” in claim 72, that one of ordinary skill in the art would readily understand that this phrase merely refers to the amount of a preparation that includes transfer factor in the claimed composition. One of ordinary skill in the art would also readily understand from the plain language of claim 72 that vitamin C must also be present in the composition in substantially the same amount.

The Office has also rejected claims 70 and 72 for including the term “substantially.” It is readily apparent to one of ordinary skill in the art that the term “substantially,” in reference to the amounts that two ingredients are present in a composition, merely provides for known tolerances in the relative amounts of ingredients in the composition.

In view of the foregoing, it is respectfully submitted that one of ordinary skill in the art would readily understand the scope and meaning of each of claims 1, 4-18, 50, 53-67, 69-73, 77

and 78. As such, these claims comply with the definiteness requirement of the second paragraph of 35 U.S.C. § 112.

It is respectfully requested that the 35 U.S.C. § 112, second paragraph, rejections of claims 1, 4-18, 50, 53-67, 69-73, 77 and 78 be withdrawn, and that each of these claims be allowed.

#### **Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 1 and 4-18 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement.

It has also been asserted that claims 1, 4-18, 50, 53-67, and 70-73 do not comply with the written description requirement of the first paragraph of 35 U.S.C. § 112.

It is respectfully submitted that the proposed amendments to claims 1, 50, 71, and 73, as well as the foregoing comments on claims 70 and 72, address each of these rejections.

Withdrawal of the 35 U.S.C. § 112, first paragraph, rejections of claims 1, 4-18, 50, 53-67, and 70-73 is respectfully solicited, as is the allowance of each of these claims.

#### **Rejections under 35 U.S.C. § 102**

Claims 1, 7, 8, 10-15, 17, 50, 56, 57, 59-64, 66, and 68-78 have been rejected under 35 U.S.C. § 102(e) for reciting subject matter that is allegedly anticipated by the subject matter disclosed on U.S. Patent 6,506,413 to Ramaekers (hereinafter "Ramaekers").

A claim is anticipated only if each and every element, as set forth in the claim, is found, either expressly or inherently described, in a single reference which qualifies as prior art under 35 U.S.C. § 102. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Ramaekers describes compositions that include transfer factor and a variety of other components for treating various disorders in animals. While Ramaekers notes that transfer factor molecules may be specific for certain antigens, including antigens of the herpes simplex viruses

(col. 1, lines 20 and 21), Ramaekers does not expressly or inherently describe a composition that includes both a blood flow-enhancing component *and* transfer factor specific for at least one pathogen (or an antigen thereof) that directly causes a cardiovascular disorder that is to be treated with the composition, as recited in amended independent claims 1 and 50. Therefore, Ramaekers does not describe “[t]he identical invention . . . in as complete detail as is contained in the claim.” *Richardson*, 9 USPQ2d at 1920.

Accordingly, it is respectfully submitted that Ramaekers does not anticipate each and every element of amended independent claim 1 or of amended independent claim 50, as would be required to maintain the 35 U.S.C. § 102(e) rejections of amended independent claims 1 and 50.

Each of claims 7, 8, 10-15, and 17 is allowable, among other reasons, for depending directly or indirectly from amended independent claim 1, which is allowable.

Claims 56, 57, 59-64, and 66 are each allowable, among other reasons, for depending directly or indirectly from amended independent claim 50, which is allowable.

It is also respectfully submitted that Ramaekers does not expressly or inherently describe a composition that includes preparation including avian transfer factor specific for at least one of HSV-I, HSV-II, *Chlamydia pneumoniae*, cytomegalovirus, and *Helicobacter pylori*, along with vitamin C, niacinamide, a form of arginine, and a form of lysine, as would be required to anticipate each and every element of independent claim 68, as proposed to be amended. Specifically, Ramaekers lacks any teaching or suggestion of a composition that includes avian transfer factor. Additionally, Ramaekers does not expressly or inherently describe a composition that includes transfer factor that is specific for a particular antigen, in combination with vitaminC, niacinamide, a form of arginine, and a form of lysine.

Therefore, it is respectfully submitted that Ramaekers does not anticipate each and every element of amended independent claim 68, as would be required to maintain the under 35 U.S.C. § 102(e) rejection of that claim.

Claims 69-71 are each allowable, among other reasons, for depending directly from independent claim 68, which is allowable.

Independent claim 72 is allowable over Ramaekers because Ramaekers lacks any express or inherent description of a composition that includes a preparation with transfer factor and vitamin C in substantially equal amounts.

Claims 73-78 are each allowable, among other reasons, for depending directly or indirectly from independent claim 72, which is allowable.

Withdrawal of the 35 U.S.C. § 102(e) rejections of claims 1, 7, 8, 10-15, 17, 50, 56, 57, 59-64, 66, and 68-78 is respectfully requested, as is the allowance of each of these claims.

**Rejections under 35 U.S.C. § 103(a)**

Claims 4-6, 9, 16-18, 53-55, 58, 65-67, and 69 have been rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Ramaekers in View of Tokoro

Claims 4-6, 9, 16-18, 53-55, 58, and 65-67 have been rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the teachings of Ramaekers, in view of the subject matter taught in U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

Each of claims 4-6, 9, and 16-18 is allowable, among other reasons, for depending directly or indirectly from independent claim 1, which is allowable.

Claims 53-55, 58, and 65-67 are each allowable, among other reasons, for depending from independent claim 50, which is allowable.

Moreover, it is respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 4-6, 9, 16-18, 53-55, 58, or 65-67.

Tokoro has been relied because it purportedly teaches transfer factor from an egg of a hen. It is again noted that Tokoro does not teach or suggest transfer factor. Instead, the teachings of Tokoro are limited to a “transfer factor-like component,” which the prior art makes abundantly clear is something different from transfer factor. Dunnick, W., et al., “Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980), at page 65.

As Tokoro does not include any teaching or suggestion with respect to transfer factor, it is respectfully submitted that, without the benefit of hindsight provided by the claims of the above-referenced application, one of ordinary skill in the art wouldn't have been motivated to combine teachings of Ramaekers with teachings from Tokoro.

Therefore, a *prima facie* case of obviousness has not been established against any of claims 4-6, 9, 16-18, 53-55, 58, and 65-67.

Ramaekers, Kirkpatrick, and Vercellotti

Claims 9 and 58 have been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is assertedly unpatentable over teachings from Ramaekers, in view of teachings from U.S. Patent 5,470,835 to Kirkpatrick et al. (hereinafter “Kirkpatrick”) and, further, in view of the subject matter taught in Vercellotti, GM, “Microbes, inflammation and atherosclerosis: will old pathology lessons guide new therapies?” Trans. Am. Clin. Climatol. Assoc 112:215-22 (2001) (Abstract) (hereinafter “Vercellotti”).

Claim 9 is allowable, among other reasons, for depending directly from independent claim 1, which is allowable.

Claim 58 is allowable, among other reasons, for depending directly from independent claim 50, which is allowable.

Moreover, it is respectfully submitted that Vercellotti teaches away from the purported combination of referenced teachings and, as such, that without the benefit of hindsight that the disclosure and claims of the above-referenced application have provided to the Office, one of ordinary skill in the art wouldn't have had a reasonable expectation that the asserted combination of reference teachings would be successful or been motivated to combine the teachings of Ramaekers, Kirkpatrick, and Vercellotti in the manner that has been asserted. Specifically, Vercellotti teaches that

“microbes contain molecules that mimic host cellular components . . . An immune response to a pathogen may cross react with vessel wall cellular structures. This immune response enhanced by infection may lead to high levels of cross reacting auto-antibodies or auto-aggressive T-cells. . . . Thus, pathogens might contribute to the atherosclerotic process by promoting inflammatory responses.

From this statement, as of the earliest date to which a claim for priority has been made in the above-referenced application, one of ordinary skill in the art could have expected nothing more than for transfer factor to promote an autoimmune response in a treated subject with coronary artery disease and, thus, to do nothing more than increase inflammation in the treated subject. As such, one of ordinary skill in the art wouldn't have had any reason to expect that a composition that includes transfer factor could be useful in treating coronary artery disease, or any motivation to combine the teachings of Ramaekers, Kirkpatrick, and Vercellotti in the manner that has been asserted.

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against claim 9 or claim 58, and that both of these claims are allowable under 35 U.S.C. § 103(a).

#### Ramaekers in View of Singh

Claims 16 and 65 stand rejected under 35 U.S.C. § 103(a) for being directed to subject matter that is purportedly unpatentable over the subject matter taught in Ramaekers, in view of teachings from Singh et al., “Coenzyme Q in cardiovascular disease” Assoc Physicians India. (Mar 1998) 46(3):299-306 (Abstract) (hereinafter “Singh”).

Claim 16 is allowable, among other reasons, or depending from independent claim 1, which is allowable, while claim 65 is allowable, among other reasons, for depending from independent claim 50, which is allowable.

Claims 16 and 65 are further allowable since teachings from Ramaekers and Singh do not support a *prima facie* case of obviousness against them.

#### Ramaekers in View of Pearson

Claim 69 has been rejected under 35 U.S.C. § 103(a) for reciting subject matter that is allegedly unpatentable over the teachings of Ramaekers, in view of teachings from U.S. Patent 6,693,094 to Pearson et al. (hereinafter “Pearson”).

Claim 69 is allowable, among other reasons, for depending directly from claim 68, which is allowable.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 4-6, 9, 16-18, 53-55, 58, 65-67, and 69 be withdrawn, and that each of these claims be allowed.

#### **Entry of Amendments**

Entry of the proposed claim amendments is respectfully requested. It is respectfully submitted that the proposed amendments to the claims reduce the number of issues that remain for purposes of appeal without introducing new matter into the application or necessitating an additional search.

In the event that the proposed amendments to the claims are not entered, their entry is respectfully solicited upon the filing of a Notice of Appeal in the above-referenced application.

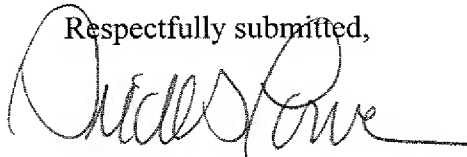
#### **CONCLUSION**

It is respectfully submitted that each of claims 1, 4-18, 50, and 53-78 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing



allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power". The signature is fluid and cursive, with a large initial "B" and "P".

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